

Biosimilars:

What Patients Need To Know

Biosimilars are a type of biologic medication that is **safe** and **effective** for the treatment of many chronic and severe conditions, including:



Chronic skin diseases

(such as psoriasis)



Macular Degeneration



Chronic bowel diseases

(such as colitis, Crohn's disease, and irritable bowel disorder)



Arthritis



Diabetes



Kidney conditions



Some cancers

(such as breast, lung, and colon)

A biosimilar is very similar, but not identical, to an original biologic medication (also known as a reference product) that FDA has already approved. For biosimilars to be approved by FDA, studies must show that there are no differences in the safety and effectiveness of biosimilars and the original biologics.

Both a biosimilar and its original biologic:

- Are made from the same types of sources (e.g., living sources)
- Provide the same benefits when treating diseases or medical conditions
- Are given at the same strength and dosage
- Are not expected to cause new or worsening side effects

FDA has approved many biosimilars and expects to approve more in the future. For more information about individual biosimilars and the conditions they treat, please visit <https://purplebooksearch.fda.gov>.

What are biologic medications? How are they different from other types of medications?

Most biologics are made from living sources, such as animal cells and microorganisms like bacteria or yeast. Because biologics generally come from living sources and have natural differences, they can be more complicated to produce than drugs made from chemicals. Drugs made from chemicals, such as aspirin, can generally be more easily copied.

What are interchangeable biosimilars?

An interchangeable product is a biosimilar that may be substituted without consulting the prescribing doctor, because it meets additional requirements related to the potential for automatic substitution. This practice is called "pharmacy-level substitution" and is subject to state law.

Both biosimilars and interchangeable biosimilars are as safe and effective as the original product they were compared to.

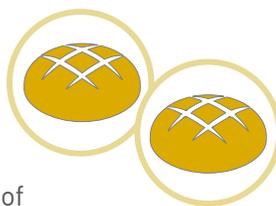
For more information on biosimilars, visit

www.FDA.gov/biosimilars

and talk to your doctor to learn more.



All biologic medications, including biosimilars, are similar to loaves of bread if they were made with the same recipe: No one loaf is an exact copy of another, but they are all the same type of bread. The same is true for biologics: Each batch of a biologic medication is made with a mix of ingredients that include living sources. Because living sources have slight variations, each batch is not an exact copy, but each batch provides the same treatment benefits.



Are biosimilars the same as generic drugs?

Biosimilars and generics are both versions of medications already approved by FDA. Biosimilars are like generics in some ways, but there are differences. Both biosimilars and generics may offer more affordable treatment options to more patients.



Biosimilars

Generally made from living sources

Require a specialized process to produce

Very similar, but not identical, to original biologics

Faster development process using public information from original biologic approval

Usually less expensive than original biologics



Generics

Generally made from chemicals

Have a simpler process to copy

Copy of brand-name drugs

Faster development process using public information from brand-name drug approval

Usually less expensive than brand-name drugs

Biosimilars may be available at a lower cost than the original biologics. Similar to generic drugs, biosimilars may cost less because manufacturers rely on FDA's finding that the original biologics are safe and effective. The lower cost is not a reflection of the safety or effectiveness of biosimilars. Because of the lower cost, biosimilars may be covered by more insurance companies and offer patients additional treatment options.

Why aren't biosimilars identical to the original biologics?

Because most biologics are made from living sources, it is normal for both biosimilars and original biologics to have minor differences between batches of the same medication. This means that biologics cannot be copied exactly, and that is why biosimilars are not identical to the original biologic.

FDA carefully reviews the differences between the original biologic and the biosimilar to ensure that biosimilars are as safe and effective as the original biologics.

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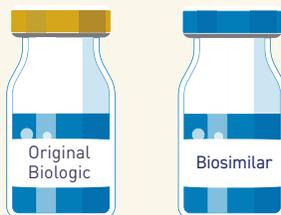


Biosimilars are safe and effective. As it does with all medication approvals, FDA carefully reviews the data provided by pharmaceutical companies and takes a number of steps to ensure that all biosimilars meet standards for patient use. Patients and health care providers can rely on a biosimilar to be as safe and effective as the original biologic. FDA takes the same precautions to help ensure the safety and effectiveness of biosimilars as it does for all medications.

Before approving a biosimilar, FDA:



Carefully reviews data, studies, and tests to decide whether a biosimilar meets FDA's high standards for approval



Ensures that manufacturers show that there are no differences in side effects, including that the side effects of the biosimilar are not more frequent or more severe than those of the original biologic

After approval, FDA:



Continues to check on the quality of the biosimilar production



Reviews reports from patients and health care providers on the biosimilar's safety and effectiveness

As with all treatment decisions, you should talk to your health care providers and check other trusted sources of information related to your specific condition to learn more about biosimilar treatment options.

Biosimilars are a growing field of critical treatment options for a range of conditions. FDA is committed to educating patients and caregivers about biosimilars so they understand all potential treatment options. More detailed information on the approval process and published studies is available for doctors and patients on the FDA biosimilars website, www.fda.gov/biosimilars.

Why would a patient switch from an original biologic to a biosimilar?

A biosimilar is not safer or more effective than the original biologic, but a patient might switch to a biosimilar because of a change in insurance coverage or to save money. Depending on the law in your state, a pharmacist may give you an interchangeable biosimilar, much like they would give you a generic. FDA does not control the cost of drugs, but you can learn more about the price of a specific biosimilar by contacting your pharmacy or insurance company.



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